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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,486	10/30/2003	George Gullickson	P-11191.00	7401
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER PAPAPIETRO, JACQUELINE M	
			ART UNIT	PAPER NUMBER
			3739	
			MAIL DATE	DELIVERY MODE
			11/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/697,486

Applicant(s)

GULLICKSON ET AL.

Examiner

Jacqueline Papapietro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9 and 14-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo (US 6530897 B2) in view of Pearson et al (US 2003/0212394 A1).

Regarding claims 1-9 and 14-23, Nardeo discloses a steerable catheter comprising: an elongated catheter body (100, Fig 7) including a proximal end, a distal segment (Fig 1) and a deflection lumen extending from the proximal end toward the distal segment (15, Figs 1 and 2); a handle (200, Fig 7) coupled to the catheter body proximal end and including a longitudinal axis; and a deflection mechanism (220) for selectively inducing a bend in the catheter body; the deflection mechanism comprising: an elongated deflection wire (50) extending within the deflection lumen of the catheter body and into the handle; a thumb wheel (steering dial 220) mounted within the handle; wherein rotation of the thumb wheel in a first direction moves the deflection wire proximally through the deflection lumen inducing a first bend of the catheter body, and a rotation of the thumb wheel in a second direction moves the deflection wire, inducing a second bend of the catheter body (column 4 lines 63-66); wherein the handle further includes a first major side (213, Fig 6) and a second major side (214) and the thumb wheel is disposed intermediate the first major side and the second major side (see Fig 6); wherein the handle further includes a first handle body portion and a second handle body portion joined along a plane substantially perpendicular to the thumb wheel axis;

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the first handle body portion and the second handle body portion capturing the thumb wheel there between (see figs 6-8); wherein the deflection mechanism further comprises a securing mechanism (locking device 230, Fig 7) selectively engageable in use from either the first major side or the second major side of the handle to apply a friction force, which holds the thumb wheel preventing further rotation of the thumb wheel (column 5 lines 23-29); wherein the handle further includes a first minor side (215, Fig 7) extending between the first major side and the second major side and a first thumb wheel window (218) extending through the first minor side through which a portion of the thumb wheel is exposed (see Figs 6-8); wherein the handle further includes a second minor side opposite the first minor side (216, Fig 7), and a second thumb wheel window (see Figs 7 and 8) extending through the second minor side through which a second portion of the thumb wheel is exposed, wherein the thumb wheel includes a side wall forming an outer rim, the outer rim being exposed through the first thumb wheel window (see Figs 7-8) and the second thumb wheel window, wherein the outer rim includes serrations (222, Fig 7) and first and second indentations (any of the indentations formed by teeth 222, see Fig 7).

Nardeo discloses a deflection mechanism wherein rotation of the wheel is translated into a forward-and-back motion of the deflection wire. Nardeo also discloses that the wire may terminate on a gear or other device mechanically controlled by the motion of the thumb wheel (column 4 line 67- column 5 line 2). Nardeo does not specifically disclose a guide track, rack arm, runners, pinion gear, or linear rack.

Pearson discloses an ablation apparatus that is steerable using deflection mechanisms (25, Figs 3 and 4), which can include pull wires, latch and lock mechanisms, including a rack and pinion (see paragraphs 0069-0071). Rack and pinion mechanisms move along a linear path. The limitation "substantially aligned with the deflection mechanism" is sufficiently broad to include the configuration disclosed by Nardeo in view of Pearson. Pearson teaches that it is old and well known in the art to use rack and pinion mechanisms as deflection mechanisms in catheters. At the time the invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to substitute a deflection mechanism including a guide track, pinion gear, and rack arm as taught by Pearson for the deflection mechanism disclosed by Nardeo in order to deflect the distal end of the catheter and to obtain predictable results.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo in view of Pearson as applied to claim 9 above, and further in view of Thompson et al (US 5358478).

Nardeo in view of Pearson discloses the catheter of claim 9, as described above, but does not disclose a resilient compressible member. Thompson teaches a steerable catheter (10) with a thumb wheel (18 and 34, Fig 1), deflection wire (58), and deflection mechanism (Fig 2) comprising a securing mechanism (locking lever 38, Fig 1) selectively engageable to apply friction, which holds the thumb wheel and prevents rotation of the thumb wheel (column 4 lines 10-24). The securing mechanism comprises

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a resilient compressible member (an O-ring) disposed in the gap between the thumb wheel sidewall and one of the first major side and the second major side of the handle body (column 4 lines 13-14). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the locking mechanism of Thompson in the catheter of Nardeo in view of Pearson in order to prevent rotation of the wheel when no further bending of the catheter is desired.

Regarding claims 11-13, where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPW 7, 9 (CCPA 1975). Applicant has not disclosed that the securing mechanism of the instant application is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the securing mechanism of Nardeo or Thompson, or the securing mechanism of the instant application because both mechanisms successfully stop the thumb wheel from further rotation. Therefore, it would have been an obvious matter of design choice to modify Nardeo to obtain the invention as specified in claims 11-13.

Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nardeo in view of Pearson as applied to claim 1 above, and further in view of Biggs (US 6030360).

Nardeo in view of Pearson discloses the catheter of claim 1, with the features described above, wherein the handle is ergonomically designed (column 4 lines 51-52), but does not specifically disclose a narrowed waist. Biggs teaches a steerable catheter wherein a handle includes a first major (312U, Fig 1B) side and a second major side (312L); the first and second major sides forming a thumb wheel support segment and a grasping segment extending proximally from the support segment (see Figs 1A-2B); the grasping segment including a narrowed waist (see Fig 2A) facilitating ergonomic handling. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the narrowed waist of Biggs in the steerable catheter of Nardeo in view of Pearson in order to make it easier and more comfortable for the user to hold the instrument.

Response to Arguments

Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Papapietro whose telephone number is (571) 272-1546. The examiner can normally be reached on M-F 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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